UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,288	11/09/2001	D. Wade Walke	LEX-0268-USA	6712

7590 07/15/2003

Lance K. Ishimoto
Lexicon Genetics Incorporated
4000 Research Forest Drive
The Woodlands, TX 77381

EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY.

Office Action Summary	Application No.	Applicant(s)	
	10/038,288	WALKE ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5 and 7-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence alignments* .

DETAILED ACTION

Application Status

[1] Claims 5 and 7-10 are pending in the application.

[2] Applicant's election without traverse of Group V, original claims 5 and 7, cancellation of claims 1-4 and 6, and addition of claims 8-10 in Paper No. 9, filed May 27, 2003, is acknowledged.

Change of Inventorship

[3] In view of the papers filed May 27, 2003 (see page 4 of Paper No. 9), the inventorship in this nonprovisional application has been changed by the deletion of inventor Nathaniel L. Wilganowski.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Oath/Declaration

[4] It is noted that the citizenship of inventor Nathaniel L. Wilganowski has not been listed on the Declaration as required by 37 CFR 1.63(a). However, as Nanthaniel L. Wilganowski is no longer a joint inventor of the claimed invention (see item 3 above), this information is not required.

Information Disclosure Statement

[5] Receipt of Information Disclosure Statements filed as Paper Nos. 3 and 7 is acknowledged. The references cited on Forms PTO-1449 have been considered by the examiner and copies of Forms PTO-1449 are attached to the instant Office action.

Claim Rejection(s) - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[6] Claims 5 and 7-10 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claim 5 is drawn to an isolated polynucleotide comprising at least 24 contiguous bases from SEQ ID NO:6. Claim 7 is drawn to an isolated recombinant expression vector comprising a nucleotide sequence encoding SEQ ID NO:7. Claim 8 limits the polynucleotide of claim 5 to a polynucleotide comprising SEQ ID NO:6. Claim 9 limits the recombinant expression vector of claim 7 to a recombinant expression vector comprising SEQ ID NO:6. Claim 10 is drawn to a host cell comprising the recombinant expression vector of claim 7.

Regarding a substantial utility for the claimed polynucleotide, vector, and host cell, applicant asserts the polypeptide of SEQ ID NO:7 encoded by the nucleic acid of SEQ ID NO:6 shares sequence similarity with mammalian secreted proteins (page 1, lines 10 and 11 of the specification) and shares structural similarity to the human protein hormones chorionic gonadotrophin and follicle stimulating hormone (page 2, lines 4-7 of the specification). It is noted that applicant has presented no explicit assertion of the function of the polypeptide of SEQ ID NO:7. Even if applicant's statement that SEQ ID NO:7, encoded by the nucleic acid of SEQ ID NO:6, shares sequence similarity with human chorionic gonadotrophin and follicle stimulating hormone is to be construed as an implied assertion of function – which it is not - further experimentation would be required to establish a real-world use for the polypeptide and encoding nucleic acid as explained in detail below. It is well known in the art that the human glycoprotein hormones chorionic gonadotrophin (CG), follicle stimulating hormone (FSH), luteinizing hormone (LH), and thyroid-stimulating hormone (TSH) are heterodimeric proteins formed by noncovalent association of an alpha and beta subunit (see e.g., Lustbader et al. *Recent Prog Horm Res* 53:396). The amino acid sequences of the alpha subunits of CG, FSH, LH, and TSH are identical within a given species with distinct, but structurally homologous beta subunits that confer receptor binding specificity (see e.g., Lustbader et al. *Recent Prog Horm Res* 53:396). A sequence search reveals that SEQ

ID NO:7 does not share the highest degree of identity with human CG or FSH and instead shares the highest percentage amino acid identity (18.6%) with bovine (GenBank Accession Number A93489) and sheep (GenBank Accession Number S06935) glycoprotein hormone alpha subunit (see attached sequence alignments). As the state of the art acknowledges that alpha subunits are identical within a given species, one of ordinary skill in the art would reasonably expect SEQ ID NO:7 to share a high, if not the highest, degree of identity or similarity to a human glycoprotein hormone subunit. However, as stated above, this is not the case. Even if SEQ ID NO:7 is a human CG or FSH subunit, it is noted that the specification provides no indication as to whether the polypeptide of SEQ ID NO:7 is an alpha or beta subunit of human CG or FSH. While SEQ ID NO:7 shares sequence identity with bovine and sheep glycoprotein hormone alpha subunit, this is no indication that the polypeptide of SEQ ID NO:7 is also an *alpha* subunit as the prior art teaches that the alpha and beta subunits of glycoprotein hormones are homologous (see e.g., Lustbader et al. *Recent Prog Horm Res* 53:396). Because SEQ ID NO:7 shares such low percentage identity to bovine and sheep glycoprotein hormone alpha subunit, it is possible that the SEQ ID NO:7 is a glycoprotein hormone beta subunit. As such, even if SEQ ID NO:7 is a human CG or FSH subunit, further experimentation would be required to determine whether SEQ ID NO:7 is an alpha or beta subunit of a glycoprotein hormone.

Furthermore, even if applicant's statement that SEQ ID NO:7, encoded by the nucleic acid of SEQ ID NO:6, shares sequence similarity with human CG and FSH is to be construed as an implied assertion of function – which it is not - the state of the art indicates that functional assignment based on sequence similarity or identity alone, particularly in the instant case where the sequences share low sequence identity, can lead to an erroneous functional assignment. As evidence of the state of the art, Brenner (*Trends Genet* 15 :132-133) teaches that it is impossible to determine the reliability of a functional assignment of a protein without verification by laboratory experiments (page 132, left column). A specific example of erroneous functional assignment is provided by Scott et al. (*Nat Genet* 21:440-443) who teach an erroneous functional assignment of a protein based on 45% sequence identity to a human sulfate transporter (page 440, left column, middle). Scott et al. teach "[w]e conclude that pendrin does

not function as a sulfate transporter, as suggested by its close homology to other sulfate transporters, but instead functions as a sodium-independent transporter of chloride and iodide. These results underscore the importance of confirming the function of newly identified gene products even when database searches reveal significant sequence homology to proteins of known function" (page 441, left column, bottom). Therefore, even if applicant's statement that SEQ ID NO:7, encoded by the nucleic acid of SEQ ID NO:6, shares sequence similarity with human CG and FSH is to be construed as an implied assertion of function – which it is not - based on the vague functional definition of SEQ ID NO:7, the low amino acid sequence identity of SEQ ID NO:7 with bovine and sheep glycoprotein hormone alpha subunits, and in view of the teachings of Brenner and Scott et al., a skilled artisan would recognize that further research is required to confirm the function of the polypeptide of SEQ ID NO:7 as human CG or FSH.

Regarding a specific utility for the claimed nucleic acids, applicant asserts various utilities for the claimed nucleic acids including protein expression, use as hybridization probes, antisense oligonucleotides, detection of mutations or polymorphisms for disease diagnosis, use as a therapeutic agent, and a drug target. The use of a nucleic acid for protein expression, hybridization, or antisense is not specific as virtually *any* nucleic acid has utility for protein expression or for use as hybridization probes and antisense oligonucleotides. Furthermore, regarding the use of the claimed nucleic acid for the detection of mutation for disease diagnosis or for use as a therapeutic agent and drug target, it is noted that the specification fails to disclose a nexus between the claimed nucleic acid and a *specific* disease state that may be useful for identifying, diagnosing, or therapeutically treating a disease state or condition. Therefore, the asserted utilities are not specific to the claimed nucleic acids and are instead general utilities that would be applicable to the broad class of nucleic acids and/or would require further experimentation to identify or confirm a "real world" context of use. Thus, the claimed nucleic acids have no specific and substantial asserted utility.

Based on the foregoing statements, it is unclear as to how the polypeptide of SEQ ID NO:7 or the encoding nucleic acid of SEQ ID NO:6 would be useful without further experimentation to identify a real-

world use. In the instant case further experimentation is required in order to identify a "real world" context of use for the polynucleotide of SEQ ID NO:6. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. Here the claimed polynucleotide is suitable only for additional research. For the reasons stated above, the claimed nucleic acid has no specific and substantial utility.

Claim Rejection(s) - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[7] Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is drawn to a genus of isolated polynucleotides *comprising* at least 24 contiguous nucleotides from SEQ ID NO:6. The written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number* of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species that are adequately described are representative of the entire genus. The specification discloses only a single representative species of the claimed genus, i.e., SEQ ID NO:6. The specification fails to disclose any other representative species of the claimed genus. The genus of

polynucleotides of claim 1 encompasses widely variant species of nucleic acids that have not been described in the specification, including full-length genes, splice variants, and nucleic acids encoding proteins potentially having a wide variety of functions. As such, neither the description of the structure of SEQ ID NO:6 nor the disclosure of a structural feature present in all members of the genus, i.e., at least 24 contiguous nucleotides of SEQ ID NO:1, is sufficient to be representative of the attributes and features of the entire genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

[8] Claims 5 and 7-10 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in item 6 above, one skilled in the art clearly would not know how to use the claimed invention.

[9] Even if applicant demonstrates the nucleic acids, vectors, and host cell encoding SEQ ID NO:7 have a specific and substantial or well-established utility, the following rejection still applies. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding SEQ ID NO:7 does not reasonably provide enablement for all isolated polynucleotides comprising at least 24 nucleotides of SEQ ID NO:6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 5 is so broad as to encompass *all* isolated polynucleotides comprising at least 24 nucleotides of SEQ ID NO:6. Undue experimentation would be required for a skilled artisan to make and/or use the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of

the art, and (8) the breadth of the claim(s). The Factors most relevant to the instant rejection are addressed below.

- The claim is overly broad in scope: Claim 5 is so broad as to encompass *all* isolated polynucleotides comprising at least 24 nucleotides of SEQ ID NO:6. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids broadly encompassed by the claims. The claim is so broad as to encompass variants and fragments of SEQ ID NO:6 including nucleic acids encoding polypeptides having any function. In this case, the disclosure is limited to the isolated nucleic acid of SEQ ID NO:6.
- The lack of guidance and working examples: The specification provides a single working example of a nucleic acid comprising 24 contiguous nucleotides of SEQ ID NO:6, i.e., SEQ ID NO:6 encoding the polypeptide of SEQ ID NO:7. This single working example fails to provide the necessary guidance for making and/or using the entire scope of claimed nucleic acids, which encompasses variants and fragments of SEQ ID NO:6 including nucleic acids encoding polypeptides having *any* function. The specification fails to provide guidance regarding those regions or fragments of at least 24 contiguous nucleotides of SEQ ID NO:6 that are necessary for CG and/or FSH activity and which of those fragments may be elongated with additional nucleotides and maintain said activities. Also, the specification fails to provide guidance as to methods of isolating and/or using those nucleic acids that do not encode polypeptides having CG and/or FSH activity, i.e., nucleic acids encoding non-functional polypeptides or those polypeptides having function other than CG and/or FSH activity.
- The high degree of unpredictability of the art: The nucleotide sequence of an encoding nucleic acid determines an encoded protein's structural and functional properties. Predictability of which potential changes can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within an encoding nucleic acid's sequence where nucleotide modifications can be made with a

reasonable expectation of success in obtaining an encoded polypeptide with the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. In this case, the necessary guidance for altering the nucleotide sequence of SEQ ID NO:6 with an expectation of maintaining CG and/or FSH activity has not been provided in the specification. Thus, a skilled artisan would recognize the high degree of unpredictability that *all* nucleic acids comprising a fragment of as few as 24 nucleotides of a 255 nucleotide coding sequence, including fragments and variants of SEQ ID NO:6, would retain the ability to encode a protein having CG and/or FSH activity.

- The state of the prior art: The state of the prior art provides evidence for the high degree of unpredictability in altering a polynucleotide sequence with an expectation that the encoded polypeptide will maintain the desired activity/utility. Branden et al. (Introduction to Protein Structure, Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). As a specific example, Witkowski et al. (*Biochemistry* 38:11643-11650) teach that alteration of an encoding nucleic acid to mutate a single amino acid results in conversion of their polypeptide's enzymatic activity from a beta-ketoacyl synthase to a malonyl decarboxylase (see e.g., Table 1, page 11647). Thus, the prior art acknowledges that the effects of altering an amino acid sequence of a polypeptide are highly unpredictable and altering an encoding nucleic acid to substitute even a *single* amino acid may completely alter a protein's function.
- The amount of experimentation required is undue: While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. In view of the overly broad scope of the claim, the lack of guidance and working examples provided in the specification, and the high degree of

unpredictability as evidenced by the state of the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of claimed nucleic acids.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re* Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re* Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejection(s) - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

[10] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application number 60/249,044, filed November 15, 2000, is acknowledged. The sequences of SEQ ID NO:6 and SEQ ID NO:7 are disclosed in provisional application number 60/249,044. Applicant is granted the benefit of the filing date of the provisional application and the rejection(s) stated below have been made based on the earliest priority date of November 15, 2000.

[11] Claims 5 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Database GenBank Accession Number AC021985 (version AC021985.1 GI:6731254). Claim 5 is drawn to an isolated polynucleotide comprising at least 24 contiguous bases from SEQ ID NO:6. Claim 8 limits the polynucleotide of claim 5 to an isolated polynucleotide comprising SEQ ID NO:6. Database GenBank Accession Number AC021985 teaches an isolated nucleic acid comprising a nucleotide sequence that is

100% identical to the full length of SEQ ID NO:6 (see attached sequence comparison). This anticipates claims 5 and 8 as written.

[12] Claims 5 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Database GenBank Accession Number AC016488 (version AC016488.3 GI:6692351). Claims 5 and 8 are drawn to an isolated polynucleotide as described in item 11 above. Database GenBank Accession Number AC016488 teaches an isolated nucleic acid comprising a nucleotide sequence that is 100% identical to the full length of SEQ ID NO:6 (see attached sequence comparison). This anticipates claims 5 and 8 as written.

[13] Claims 5 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Database GenBank Accession Number AC048370 (version AC048370.2 GI:7770518). Claims 5 and 8 are drawn to an isolated polynucleotide as described in item 11 above. Database GenBank Accession Number AC048370 teaches an isolated nucleic acid comprising a nucleotide sequence that is 100% identical to the full length of SEQ ID NO:6 (see attached sequence comparison). This anticipates claims 5 and 8 as written.

[14] It is noted that, while Database GenBank Accession Numbers AC021985, AC016488, and AC048370 teach their nucleic acids are present in an M13 sequencing vector having GenBank Accession Number M77815, claims 7 and 9, drawn to a recombinant *expression* vector (italics added for emphasis) comprising a nucleotide sequence encoding SEQ ID NO:7, have not been rejected as being anticipated or made obvious by any of Database GenBank Accession Numbers AC021985, AC016488, and AC048370. The art recognized meaning of the term "expression vector" is a vector comprising a constitutive or inducible promoter positioned for expression of a desired gene product. A review of GenBank Accession Number M77815 indicates that this M13 vector has no such promoter for protein expression (see "Features of M13mp18"). As such, one of ordinary skill in the art would recognize that the M13 vector having GenBank Accession Number M77815 is *not* an expression vector according to art recognized definition thereof. While the instant specification provides no specific definition of the term "expression vector", the recited expression vector clearly is intended to encompass those vectors used for protein expression and *not* sequencing vectors (see pages 22-26 of the instant specification). Thus, according to MPEP 2111, which directs the examiner to give claims their broadest reasonable interpretation consistent

with the specification and the interpretation that those skilled in the art would reach, the M13 vector having GenBank Accession Number M77815 is *not* an expression vector and to interpret the M13 vector having GenBank Accession Number M77815 as an expression vector would be unreasonable according to MPEP 2111. Furthermore, Database GenBank Accession Numbers AC021985, AC016488, and AC048370 identify their nucleic acids as chromosomal nucleic acids and do not identify their respective nucleic acids as being open reading frames. Therefore, there would be no motivation to remove the nucleic acid of Database GenBank Accession Numbers AC021985, AC016488, or AC048370 from the disclosed M13 sequencing vector and insert said nucleic acid into an expression vector. Thus, claims 7 and 9 have not been rejected as being anticipated or rendered obvious by Database GenBank Accession Numbers AC021985, AC016488, and AC048370.

Conclusion

[15] Claim status:

- Claims 5 and 7-10 are pending.
- Claims 5 and 7-10 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for official papers filed to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

07/14/03